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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,648	12/11/2003	Robert J. Garabedian	2024728-7034442001 (03-22)	9116
7590 12/27/2005			EXAMINER	
David T. Burse Bingham McCuthen, LLP Suite 1800 Three Embarcadero Center San Francisco, CA 94111-4067			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	
DATE MAILED: 12/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/734,648	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/25/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherry (U.S. Pat. No. 6,221,071 B1).

Regarding claim 1, Sherry discloses a medical probe assembly for ablating tissue, comprising:

an elongated shaft 22 having a proximal end and a distal end (Fig. 3);

an electrode array 20 mechanically coupled to the distal end of the shaft (col. 5, ln. 15-19), the electrode array comprising a plurality of needle electrodes (col. 5, ln. 45-46), at least one of which is configured to assume an outwardly curved shape when exposed to a first temperature (Fig. 3). When the electrode is deployed and heated to ablate tissue, it is inherently configured to assume an outwardly curved shape when exposed to a first temperature (col. 4, ln. 61 – col. 5, ln. 5).

Regarding claims 5 and 6, Sherry discloses the medical assembly of claim 1, wherein the first temperature is greater than body temperature and equal to a tissue ablation temperature. When the electrode is deployed and heated to ablate tissue, it is

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inherently configured to assume an outwardly curved shape when exposed to a first temperature (col. 4, ln. 61 – col. 5, ln. 5).

Regarding claims 7 and 8, Sherry discloses the medical assembly of claim 1, wherein the at least one needle is configured to assume a substantially straight shape when exposed to a second temperature that is less than the first temperature and that is body temperature. When the electrodes 14 are inside the sheath 10 and being positioned inside the body and at body temperature prior to deployment and ablation, at least one needle is inherently configured to assume a substantially straight shape when exposed to a second temperature as claimed (col. 4, ln. 53-60 and Fig. 1).

Regarding claim 14, Sherry discloses the medical probe assembly of claim 1, further comprising a cannula 10 having a lumen, wherein the shaft is reciprocatably disposed within the cannula lumen (col. 4, ln. 10-15 and Figs. 1 and 3)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5-8, 15-17, 20, 26-30, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071) in view of Zepeda (WO 99/25260). Although the Sherry reference forms the basis for valid 102(b) rejections, the claims implicitly differ from Sherry in that the Sherry electrodes do not assume different shapes in the same manner as the applicant's electrodes.

Regarding claims 1, 5, and 6 Zepeda teaches expanding an array of needle electrodes 16 using temperature-sensitive shape alloy material that assumes an outwardly curved shape when exposed to a first temperature that is greater than body temperature and equal to a tissue ablation temperature (pg. 7, ln. 20 – pg. 8, ln. 4 and Fig. 5). (col. 5, ln. 15-19 and Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the shape memory alloy electrode array of Sherry temperature-sensitive and assume an outwardly curved shape when exposed to a first temperature as claimed in view of the teaching of Zepeda as an obvious alternate way of expanding shape memory alloy electrodes that is known in the art.

Regarding claims 7 and 8, Zepeda also discloses that the temperature-sensitive needles are straight when exposed to a second temperature that is less than the first temperature and is body temperature to allow the needles to be retracted inside a sheath while being positioned inside the body (pg. 7, ln. 20 – pg. 8, ln. 4). Therefore, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the shape memory alloy electrode array of Sherry temperature-sensitive and assume a substantially straight shape when exposed to a second temperature as claimed to allow the needles to be retracted inside the sheath while being positioned inside the body.

Regarding claim 15, Sherry discloses a medical probe assembly for ablating tissue, comprising:

an elongated shaft 22 having a proximal end and a distal end (Fig. 3);

an electrode array 20 mechanically coupled to the distal end of the shaft (col. 5, ln. 15-19).

As described in the preceding rejections of claims 1 and 5-8, it would be obvious to make the shape memory alloy electrodes of Sherry to be temperature-sensitive in view of Zepeda. The electrodes of Sherry in view of Zepeda would then be configured to assume an outwardly curved shape when exposed to a first temperature, and assume a pointed tip when exposed to a second temperature less than the first temperature as shown in Figs. 3 and 1, respectively of Sherry.

Regarding claim 16, see the preceding rejection of claim 15 and the following rejection of claim 2.

Regarding claim 17, see the preceding rejection of claim 15 and Fig. 3 of Sherry.

Regarding claim 20, see the preceding rejections of claims 1, 5-8, and 15.

Regarding claim 26, see the preceding rejection of claim 14.

Regarding claim 27, Sherry discloses the assembly of claims 15 and 26 in view of Zepeda. In addition, Sherry discloses the assembly, wherein the electrode array is configured to be at least partially retracted into the cannula by displacing the shaft relative to the cannula in a proximal direction (col. 4, ln. 10-15 Figs. 1 and 3)

Regarding claims 28, 29, and 34 see the preceding rejections of claims 1, 5-8, and 15.

Regarding claim 30, the device of Sherry in view of Zepeda is only capable of being formed into the outwardly curved array after being displaced out of the sheath. Therefore, the electrode array is inherently formed into the outwardly curved array in response to the displacement of the electrode array through the diseased region.

Regarding claim 35, Sherry discloses the method of claim 28 in view of Zepeda. In addition, Zepeda teaches retracting electrode array 16 back into sheath 14 before selecting another tissue region to treat (pg. 13, ln. 27 – pg. 14, ln. 3). Retracting the electrode array and stopping the ablation energy inherently cools the electrodes and causes them to reform into a single pointed tip again in response to the first temperature. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of treatment as claimed with the device of Sherry in view of Zepeda also in view of the teaching of Zepeda in order to more easily move the device to treat multiple tissue regions.

Regarding claim 36, Sherry discloses the method of claim 28 in view of Zepeda. In addition, Sherry discloses treating tumors (col. 4, ln. 3-5).

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Claims 2-4 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071) in view of Zepeda ('260) and further in view of Sharkey (U.S. PGPub 2001/0031963).

Regarding claim 2, see the following rejection of claim 2.

Regarding claims 3-4 and 18-19, see the following rejections of claims 3-4.

Claims 9-13, 20-25, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071) in view of Zepeda ('260) and further in view of Shafirstein (U.S. Pat. No. 6,780,177 B2).

Regarding claims 9-13, 20-25, and 31-33 see the following rejections of claims 9-13.

Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071).

Regarding claim 2, Sherry discloses the medical probe assembly of claim 1 but is silent on the rigidity of the shaft 22. At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the shaft rigid because applicant has not disclosed any criticality or unexpected result associated with this property. Furthermore, one of ordinary skill in the art would have expected applicant's invention to perform equally well with the claimed shaft or the shaft of Sherry because both types of shafts are capable of deploying the electrodes and treating a patient equally well.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071) in view of Sharkey (U.S. PGPub 2001/0031963).

Regarding claim 3, Sherry discloses the medical probe assembly of claim 1, wherein the at least one needle electrode comprises a nickel-titanium alloy (col. 4, ln. 61-65) but not specifically Nitinol. Sharkey, however, teaches a medical probe assembly for ablating tissue wherein at least one needle electrode comprises Nitinol (pg. 8, ¶ 96). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the needle electrode of Sherry from Nitinol in view of the teaching of Sharkey as an obvious specific type of nickel-titanium alloy that is well-known in the art.

Regarding claim 4, Sherry discloses the medical probe assembly of claim 1. The claim differs from Sherry in calling for the needle electrode to be bi-metallic. Sharkey, however, teaches a temperature sensitive bi-metallic needle electrode as an alternate means of making an electrode curve outwardly (pg. 8, ¶ 95). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the electrodes of Sherry bi-metallic in view of the teaching of Sharkey as an obvious alternate means of making electrodes curve outwardly that is known in the art.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sherry ('071) in view of Shafirstein (U.S. Pat. No. 6,780,177 B2).

Regarding claim 9, Sherry discloses the medical probe assembly of claim 1, further comprising a deployment member 30, the deployment member configured to linearly expand (col. 6, ln. 17-30 and Figs. 6A-6B). The claim differs from Sherry in calling for the deployment member to be mechanically coupled between the electrode array and the shaft, and to expand when exposed to a third temperature. Shafirstein, however, teaches a medical probe assembly for ablating tissue, wherein a deployment member 32 is mechanically coupled between an electrode 30 and a shaft, the deployment member configured to linearly expand when exposed to a third temperature (col. 5, ln. 59 – col. 6, ln. 7 and Fig. 6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the deployment member of Sherry to be coupled between the electrode array and the shaft, the deployment member configured to linearly expand when exposed to a third temperature, in view of the teaching of Shafirstein as an obvious alternate method of expanding a spring to deploy electrodes that is known in the art.

Regarding claims 10 and 11, Sherry discloses the medical probe assembly of claim 1, and the assembly of claim 9 in view of Shafirstein. Since the deployment member of Shafirstein expands in response to a heating element, it would be obvious and require only routine skill in the art to configure the deployment member to expand when exposed to a temperature greater than body temperature and equal to a tissue ablation temperature. In addition, it would be obvious and require only routine skill in the art to configure the deployment member to expand when exposed to a temperature different from this claimed first temperature.

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Regarding claims 12 and 13, Sherry discloses the medical probe assembly of claim 1, and the assembly of claim 9 in view of Shafirstein. In addition, the deployment member of Shafirstein comprises a Nitinol spring (col. 6, ln. 4-5 and Fig. 6).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 5827276 A	USPAT	LeVeen; Robert F. et al.
US 6063082 A	USPAT	DeVore; Lauri et al.
US 6575967 B1	USPAT	Leveen; Robert F. et al.
US 6905480 B2	USPAT	McGuckin, Jr.; James F. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/21/05

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER